

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

RICHARD MCLAUGHLIN,
Plaintiff,

v.

MERCK & CO., INC.,
MERCK SHARP & DOHME CORP.,
ORGANON & CO., and ORGANON, LLC,
Defendants.

CIVIL ACTION
NO. 22-40041-TSH

MEMORANDUM OF DECISION AND ORDER

March 31, 2023

Hillman, S.D.J.

Background

Richard McLaughlin (“McLaughlin” or “Plaintiff”) has brought this action against Merck & Co., Inc. “Merck & Co.”, Merck Sharp & Dohme Corp. (“MS&D”), Organon & Co. (“Organon”), and Organon LLC (“OLLC” and together with Merck & Co., MS&D and Organon, collectively “Merck Defendants” or “Merck”), to recover for injuries allegedly suffered after prolonged ingestion of the Merck Defendant’s prescription drug, SINGULAIR® (“Singulair”). McLaughlin has asserted claims against the Merck Defendants for: Breach of Warranty – Design Defect (Count I); Breach of Warranty – Failure to Warn (Count II); Negligence (Count III); Misrepresentation (Count IV); and Breach of Express Warranty (Count

V). McLaughlin's claims are based on his assertion that Singulair was unreasonably dangerous when manufactured and inadequately labeled to warn users of its possible side effects.

This Memorandum of Decision and Order addresses Defendants Merck & Co., Inc., Merck Sharp & Dohme Corp., Organon & Co., and Organon, LLC's Motion to Dismiss (Docket No. 16). For the reasons set forth below, that motion is *denied*.

Facts¹

In 1996, the Merck Defendants applied to the Food and Drug Administration ("FDA") for a patent on a new anti-asthmatic drug, Singulair. The Singulair patent was approved that same year, and Merck began selling the drug in 1998. As is commonplace with prescription drugs, re-launch tests revealed several possible side effects and Merck was required to adequately convey those risks on the Singulair warning label in accordance with FDA policy. Although the parties dispute the frequency, adequacy, and accuracy of changes made to the Singulair label between 1996 and 2012, it is undisputed that Merck updated its label on several occasions during that time period in an effort to make the label warnings more accurate.

When Merck's patent expired in 2012, the FDA approved several generic forms of the drug and greenlit them for sale in the United States. Massachusetts law requires that pharmacies fill prescriptions with the generic form of a drug first (as a way of protecting consumers), however, patients are entitled to request Singulair by name, that is, they can request that they receive the Singulair drug manufactured by Merck.

McLaughlin was prescribed Singulair in 2018, and continued filling that prescription until 2020, when he stopped taking the drug after developing neuropsychiatric problems. McLaughlin, who is the only party able to access the information, cannot at present state with

¹ The facts of this case are drawn from McLaughlin's complaint and all subsequent briefs, affidavits (declarations), and related documents submitted by the parties.

any certainty whether he ingested Singulair or a generic form of the drug. While McLaughlin has not definitively conceded the point, it is likely that his prescriptions would have been filled with a generic version of the drug. The Merck Defendants did not manufacture, market, or sell any generic form of Singulair, in Massachusetts or elsewhere.

Although Merck's patent has expired, it has a continuing duty to update the Singulair label anytime serious adverse side effects are discovered, and its generic counterparts are required to maintain their labels at a level "substantially the same" as the Singulair label. McLaughlin alleges that his injuries were the direct result of inadequate warnings on the label of whatever drug he took because if the proper warnings had been included, he would not have taken the drug. All decisions made by Merck pertaining to label warnings are made in New Jersey or Pennsylvania.

The Merck Defendants are corporations who manufacture and sell pharmaceutical drugs. Merck & Co and MS&D are organized under the laws of New Jersey with their principal places of business in that state. Organon is a Delaware corporation and OLLC is a Delaware limited liability corporation with their principal places of business in New Jersey².

Standard of Review

"When a court's personal jurisdiction over a defendant is contested, the plaintiff has the ultimate burden of showing by a preponderance of the evidence that jurisdiction exists." *Adams v. Adams*, 601 F.3d 1, 4 (1st Cir. 2010). When a defendant moves to dismiss for lack of personal jurisdiction at the inception of a case under Federal Rule of Civil Procedure 12(b)(2), "the court may proceed to adjudication by one or another among several different methods." *Brooks v. Love*, 527 F.Supp.3d 113, 116 (D. Mass. 2021) (quoting *Boit v. Gar-Tec Prod., Inc.*, 967 F.2d

² Organon is the only member of OLLC and as noted, it is incorporated and has a principal place of business outside of Massachusetts.

671, 674 (1st Cir. 1992). The most commonly used standard, applicable in this case, is the prima facie standard. *Id.* Under this standard, a court considers “whether the plaintiff has proffered evidence that, if credited, is enough to support a finding of all facts essential to personal jurisdiction.” *Id.* Plaintiffs “ordinarily cannot rest upon the pleadings but [are] obliged to adduce evidence of specific facts” supporting jurisdiction. *Id.* Finally, in deciding whether jurisdiction is proper, courts should also “consider uncontradicted facts proffered by the defendant.” *Dillon Boiler Servs., Co. v. Soundview Vt. Holdings, LLC*, 392 F.Supp.3d 187, 190 (D. Mass. 2019).

Discussion

McLaughlin has asserted claims against the Merck Defendants for design defects, failure to warn, negligence, misrepresentation, and breach of express warranty in relation to injuries allegedly sustained from McLaughlin’s ingestion of Singulair. The Merck Defendants have moved for dismissal of this action pursuant to Federal Rule of Civil Procedure 12(b)(2) on the grounds that this Court lacks personal jurisdiction over them as any conduct by them which McLaughlin alleges caused him injury did not occur within Massachusetts, and because their contacts with Massachusetts are otherwise insufficient to render them “at home” in the Commonwealth.

McLaughlin asserts that the motion should be denied because he has established that this Court’s exercise of personal jurisdiction over the Merck Defendants would comport with both the Massachusetts long arm statute, Mass.Gen.L. ch. 223A §3 and the Due Process Clause of the Fourteenth Amendment. More specifically, he asserts that he has shown that the Merck Defendants have sufficient “minimum contacts” with Massachusetts because Merck advertised, sold, and distributed Singulair within Massachusetts for several years which should qualify as conducting substantial business within the Commonwealth for purposes of Mass.Gen.L. ch.

223A §3(d). He further asserts that this Court has jurisdiction over Merck regardless of whether he took the generic drug because Merck has a continuing duty to provide adequate warnings for Singular, and manufacturers of the generic versions of Singulair are required to adopt those same warnings.

To establish personal jurisdiction, McLaughlin must establish that the requirements of both the Massachusetts long arm statute and constitutional Due Process have been met. See *Brooks*, 527 F.Supp.3d at 116. The First Circuit has long held that Massachusetts long arm statute is “co-extensive” with the Due Process requirements of personal jurisdiction, but has recently gone further, holding that the statute may be even *more* restrictive. *A Corp. v. All Am. Plumbing, Inc.*, 812 F.3d 54, 59 (1st Cir. 2016). Accordingly, the Court must determine both whether the requirements of Massachusetts long arm statute have been met and whether exercising personal jurisdiction comports with Due Process. However, where the plaintiff fails to satisfy the requirements of Massachusetts long arm statute, the Court need not address whether the plaintiff has established that Due Process requirements have been met. *Id.*

Massachusetts Long Arm Statute

McLaughlin asserts that this Court may exercise jurisdiction over the Merck Defendants pursuant to § 3(d) of the Massachusetts long arm statute. Section 3(d) provides, in relevant part, that a court may exercise personal jurisdiction over a party that has, “act[ed] directly or by an agent, as to a cause of action in law . . . arising from the person’s . . . causing tortious interference in this commonwealth by an act . . . outside this commonwealth if he regularly” does or solicits business here. Mass.Gen.L. ch. 223A, §3(d). If McLaughlin, in fact, ingested Singulair, then there would be little question that this Court has jurisdiction over the Merck Defendants. However, based on the factual record it *unlikely* that McLaughlin ingested

Singulair. For that reason, the Court will focus on McLaughlin's assertion that even if he digested the generic form of the drug (montelukast) this Court would have jurisdiction over the Merck Defendants because he has asserted state law claims against Merck relating to the inadequacy of the warning label provided with Singulair and/or the generic drug (montelukast).

McLaughlin argues that Merck's targeted advertisement (by TV and print media) and selling of Singulair in Massachusetts are relevant contact with Massachusetts because every sale of Singulair came/comes with a warning label. Merck ultimately bears responsibility for the adequacy and accuracy of the warning label that was provided with the drug he ingested, regardless of whether it was Singulair or montelukast (because generic manufacturers are required to adopt the same warnings). Given that Merck has a continuing duty to warn consumers of the dangers of Singulair and is aware that generic manufacturers must rely on Merck for the content of their warning labels, Merck's conduct *vis a vis* his "warning label" liability claims creates sufficient contacts with the state to warrant this Court's exercise of personal jurisdiction over Merck under § 3(d).

This Court is not writing on a pristine page. In a separate proceeding pending in this Court involving the Merck Defendants, *Barnes v. Merck and Co., Inc., et al*, Civ.Act.,No. 22-10496-NMG, the plaintiff has asserted claims against the Merck Defendants identical to those asserted by McLaughlin in the instant action³. The Merck Defendants filed a motion to dismiss for lack of personal jurisdiction. This Court (Gorton, D.J.) noted that the "threshold requirement of § 3(d) is that the defendants' out-of-state act caused the plaintiff's in-state harm" and held that "[a]ctions taken by defendants outside the Commonwealth, in this case, in New Jersey and

³ The plaintiff in *Barnes* also asserts that her neuropsychiatric injuries were caused by Singulair, and that Merck knew or should have known of the risks of those injuries prior to selling that product. She has asserted claims against Merck for design defect, failure to warn, negligence, misrepresentation, and breach of express warranty.

Pennsylvania, to manufacture and create the Singulair Label are the proximate cause of plaintiff's alleged neuropsychiatric injuries suffered in Massachusetts. That is the case even if plaintiff took only the generic montelukast because the FDA requires that the generic drug label must be "identical to the warning label of its brand-name counterpart." Moreover, the brand-name drug manufacturer bears responsibility for the accuracy and adequacy of its label 'as long as the drug is on the market.' " *Barnes v. Merck & Co.*, No. CV- 22-10496-NMG, 2023 WL 35359, at *3 (D. Mass. Jan. 4, 2023). After undergoing a thorough and comprehensive discussion of the applicable requirements and factors, Judge Gorton found that: (1) the plaintiff's claims sufficiently related to Merck's "Singulair activities in Massachusetts"; (2) Merck purposefully availed itself of the privilege of conducting business in Massachusetts; and (3) exercise of jurisdiction over the Merck in Massachusetts is fair and reasonable. *Id.*, at **4-6. He then held that the requirements of § 3(d) were met and that this Court's exercise of personal jurisdiction over the Merck Defendants satisfies constitutional requirements.

Given that this action mirrors the *Barnes*' case in all relevant respect and that I am in agreement with Judge Gorton's analysis in that case, I am denying the Merck Defendants' motion to dismiss for lack of personal jurisdiction.

Conclusion

Defendants Merck & Co., Inc., Merck Sharp & Dohme Corp., Organon & Co., and Organon, LLC's Motion to Dismiss (Docket No. 16) is ***denied***.

SO ORDERED.

/s/ ***Timothy S. Hillman***
 TIMOTHY S. HILLMAN
 SENIOR DISTRICT JUDGE